

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

CAREDX, INC.)	
)	
Plaintiff,)	
)	C.A. No. 19-662 (CFC)
v.)	
)	
NATERA, INC.,)	
)	
Defendant.)	

**CAREDX’S REPLY BRIEF IN SUPPORT OF ITS
MOTION FOR PERMANENT INJUNCTION**

Dated: June 1, 2022

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CareDx respectfully requests that this Court grant its motion for a permanent injunction.

I. INTRODUCTION

Other than relying on its JMOL, Natera does not dispute that CareDx is entitled to a permanent injunction. Natera's only real objection to CareDx's proposed permanent injunction is to its scope—an objection Natera failed to articulate despite repeated requests from CareDx to engage on this issue prior to filing its brief. In its Opening Brief and accompanying declaration, CareDx detailed its attempt to avoid this very dispute—sending a proposed stipulated injunction to Natera's counsel on April 4, 2022, and following up numerous times when Natera's counsel rejected the proposal without explanation. D.I. 352 at 2; D.I. 353-1. Natera does not deny that it refused to provide an explanation as to why Natera found the injunction unacceptable and offers no explanation for this.

Natera instead waited until its Opposition Brief to provide its position on CareDx's proposed stipulation. Natera's response complains in general terms that CareDx's proposal is overbroad. As soon as CareDx had at least some notice of Natera's objections to its proposed stipulation (from its Opposition Brief), counsel sent Natera a Revised Proposed Order reflecting the Jury's findings that was designed to address Natera's concerns. The parties met and conferred regarding the revised proposal, but were not able to reach agreement, in large part because Natera

continues to object that even the revised proposal is overbroad. But the Revised Proposed Order sets forth verbatim the specific advertisements the Jury found to be intentional false advertising to the satisfaction of both parties and the Court. D.I. 329. At the charging conference, the Court ordered and the parties agreed that the Jury should be presented with the claims “advertisement by advertisement” without highlighting portions of the advertisements, but taking pieces of the advertisements at the level of specificity requested by Natera itself. 3/10, 1274:2-16. The parties presented the Court with a stipulated jury verdict form (D.I. 324) precisely to avoid disputes about the scope of the injunction and Natera’s complains about using the stipulated verdict form for the injunction should be rejected.

Accordingly, CareDx submits a Revised Proposed Order with this Reply brief and to the extent this Court finds that CareDx’s initial Proposed Order (D.I. 351-1) is overbroad, CareDx respectfully requests the Court grant its request for a permanent injunction and consider its Revised Proposed Order.¹ If Natera wishes to respond to CareDx’s Revised Proposed Order, CareDx does not oppose a surreply.

¹ CareDx is not conceding that its initial Proposed Order was overbroad—it sought to enjoin only those claims the Jury found to be false. D.I. 351-1. Natera’s partial compliance with the order after CareDx’s Opening Brief was filed indicates that Natera understands its scope. CareDx maintains that all of the false statements identified in its Opening Brief should be enjoined.

In its Opening Brief, CareDx demonstrated that it notified Natera on multiple occasions that Natera was still promoting Prospera using the advertisements found by the Jury to be false advertising and unfair competition. D.I. 353-1. While Natera kept promising to remove these advertisements, even as late as May 6, these false advertisements appeared on Natera's website. D.I. 352-1; D.I. 353. In response, Natera acknowledges its failure to remove what the Jury found to be intentional false advertising from its website (D.I. 357 at 12), but instead attempts to blame this failure on CareDx. Natera asserts that CareDx failed to notify it of these false advertisements. *See* D.I. 357 at 1 n.2 ("Natera asked that CareDx notify Natera if it found any other advertising claims it believed should be taken down.").

The burden should not be on CareDx to continually police Natera's website for lingering false claims that it committed to removing. This is particularly true because, even after CareDx alerted Natera that false advertisements still appeared on its website, Natera continued to make false claims. CareDx's repeated warnings proved futile, establishing that an injunction is necessary. Moreover, Natera is better positioned than CareDx to review and vet the claims made on its *own* website. The Jury found Natera liable for *intentionally* false advertising (D.I. 329 at 14), so the burden is on Natera to ensure that its website and promotional materials only contain truthful statements. *See Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F.Supp.2d 384, 479 (D.N.J. 2009) ("the common historical practice has been that a

prevailing plaintiff in a case of . . . false advertising will ordinarily receive injunctive relief”) (citing J. Thomas McCarthy, *Trademarks & Unfair Competition* § 30:1 (4th ed.2006) and *Lermer Germany GmbH v. Lermer Corp.*, 94 F.3d 1575, 1577 (Fed. Cir. 1996)). Natera’s consistent attempts to shift the burden of its compliance to CareDx underscores the need for an injunction here.

II. NATERA DOES NOT DISPUTE THAT CAREDX IS ENTITLED TO A PERMANENT INJUNCTION

In its Opening Brief, CareDx demonstrated that it has satisfied all four factors required for a permanent injunction: (1) CareDx has suffered irreparable harm; (2) damages are insufficient to compensate CareDx; (3) the balance of equities weigh in favor of CareDx; and (4) an injunction is in the public interest. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006); D.I. 352. In response, Natera explicitly conceded that CareDx is entitled to a statutory rebuttable presumption of irreparable harm—which Natera did not attempt to rebut—and did not argue that CareDx fails to meet any of the *eBay* factors. D.I. 357 at 2 n.3. Natera has therefore conceded that CareDx is entitled to a permanent injunction in light of the Jury’s verdict. *See, e.g., Leisure Pass N. Am., LLC v. Leisure Pass Grp., Ltd.*, No. 2:12-cv-03375 (WJM), 2013 WL 4517841, at *4 (D.N.J. Aug. 26, 2013) (finding “Plaintiff has waived its opposition to this argument by failing to respond to it.”) (citing *Duran v. Equifirst Corp.*, No. 2:09-cv-03856, 2010 WL 936199, at *3 (D.N.J.

Mar. 12, 2010); and *Griglak v. CTX Mortgage Co., LLC*, No. 09-cv-5247, 2010 WL 1424023, at *3 (D.N.J. Apr. 8, 2010)).

III. CAREDX'S PROPOSED INJUNCTION IS APPROPRIATE, ESPECIALLY IN LIGHT OF NATERA'S INTENTIONAL FALSE ADVERTISING

CareDx seeks only to enjoin those statements the Jury found to be literally false. D.I. 352 at 4; D.I. 351-1. In light of Natera's opposition, and to narrow the dispute, CareDx respectfully requests that this Court consider CareDx's Revised Proposed Order, as Delaware courts have done under similar circumstances. *See, e.g., Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 397 F.Supp.2d 537, 547 (D. Del. 2005) (granting permanent injunction where plaintiff amended its proposed order to address defendant's concerns).

A. CareDx's Proposed Injunction Would Not Restrain Lawful Speech

Although it continues to contend that CareDx's proposed injunction is overbroad, Natera concedes that “‘an injunction is not overbroad’ if it ‘*only* reaches claims that are false.’” D.I. 357 at 4 (quoting *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 598 (3d Cir. 2002)) (emphasis added by Natera). CareDx's initial Proposed Order and Revised Proposed Order are narrowly tailored to enjoin only those statements the Jury found to be literally false. D.I. 329. That a large portion of Natera's current advertising may be enjoined by CareDx's Revised Proposed Order is not due to the scope of an

injunction, but rather due to the fact that Natera centered its advertising for Prospera on false comparative claims disparaging AlloSure. D.I. 348.

Natera also objects to the Revised Proposed Order because it would enjoin Natera from “conveying in promotional, training, and/or educational materials claims that are not colorably different from the False Advertising Claims.” *See* Revised Proposed Order at 5. But courts in this district regularly enjoin parties from conduct that is “not colorably different” otherwise injunctions would be meaningless. *See Gavrieli Brands LLC v. Soto Massini (USA) Corp.*, No. 18-cv-462 (MN), 2020 WL 1443215, at *9 (D. Del. Mar. 24, 2020) (finding “not colorably different” language in permanent injunction to be appropriate).

1. Only Claims Based On The Scientific Data Presented At Trial Will Be Enjoined

The Third Circuit has rejected Natera’s argument that the proposed injunction is overbroad because it does not account for future scientific developments. D.I. 357 at 5; *see Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 949 (3d Cir. 1993) (rejecting defendant’s argument that injunction was overbroad because it would be restrained from making future, truthful superiority claims if it were to improve its motor oil, and noting that if “in the future, [defendant] should improve its motor oil to surpass [plaintiff] for viscosity breakdown, [defendant] can at that time apply for a modification of the present injunction.”) (citing *F.T.C. v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 44 (D.C. Cir. 1985)); *see also Castrol, Inc. v. Quaker*

State Corp., 977 F.2d 57, 66 (2d Cir. 1992)(“If tests supporting its [enjoined] claim do come to light, [Defendant] may move to modify or dissolve the injunction.”).

CareDx’s Revised Proposed Order would only enjoin Natera from making false claims “based on the scientific support presented at trial” (Revised Proposed Order at 1). Natera expressed concern that the Revised Proposed Order would preclude it from making the same claims that were at issue here based on different scientific studies that actually support those claims. But Natera can make such claims so long as Natera identifies the scientific support.

Natera’s accusations that CareDx is suppressing competition (D.I. 357 at 6) ring hollow where the Jury found that Natera intentionally engaged in false advertising and unfair competition. And Natera’s concern that the proposed injunction “risks preventing Natera from *ever* making statements regarding Prospera” (*id.* (emphasis in original)) are belied by the evidentiary record, which shows that CareDx was able to market AlloSure almost entirely without reference to other assays (*see e.g.*, DTX125; DTX128; DTX138), and another market entrant, Eurofins, markets its donor-derived cell-free DNA test without making any superiority claims. 3/8², 83:18-24 (Sasha King: “You know, there’s another company in the space, which Peter Maag mentioned yesterday, Eurofins, and they

² All citations to the 3/8 and 3/9 Transcripts are to the Rough Transcripts.

also have a cell-free DNA test . . . and they, you know, messaged, but they don't use a superiority claim because their data doesn't kind of back that up.""). The proposed injunction will not affect truthful and adequately-supported claims regarding Prospera.

2. Natera Agreed To The Jury Verdict Form

Natera's complaints about the proposed injunction based on the format of the Jury Verdict Form (D.I. 329) should be precluded. The Jury Verdict Form, which included screenshots of Natera's false advertisements and asked the Jury to determine whether the entire advertisement or a specific statement at issue was literally false (*id.*), was discussed at length during the charging conference, and the Court left it to the parties to agree to a mutually acceptable form. 3/10, 1276:16-1277:13. With the Court's guidance, the parties agreed to a joint Jury Verdict Form that was submitted to the Court. D.I. 324. The Jury determined that nine of Natera's claims—two specific statements ("more sensitive and specific than current assessment tools across all types of rejection" and "unparalleled precision") and seven entire advertisements—were false. D.I. 329 at 4-11, 13. Natera should not now be heard to complain that the agreed-on Verdict Form is overbroad. D.I. 357 at 5.

B. The Jury Found Claims Of Unparalleled Precision To Be Literally False

CareDx proved, and the Jury found, that Natera's superiority claim of

“Unparalleled precision” is literally false. D.I. 329 at 11. Natera argues that, notwithstanding the Jury’s finding, any injunction that prevents it from falsely claiming that Prospera has unparalleled precision is overbroad. D.I. 357 at 7-11. But unlike other questions on the Verdict Form, which asked the Jury to consider whether “the advertisement” pictured was false (*see e.g.*, D.I. 329 at 5), the Jury was specifically asked – with Natera’s agreement – whether the specific statement “Unparalleled precision” was literally false:

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CareDx Question No. 8 11

Alleged Advertising Claim H

Unparalleled precision.

Unparalleled precision.
Optimized by Prospera.

QUESTION NO. 8:
Did CareDx prove by a preponderance of the evidence that Natera is liable for false advertising for **Alleged Advertising Claim H**?

YES
(for CareDx)

☒

NO
(for Natera)

☐

JTX-7.3 (Brochure)

Id. at 11. The Jury agreed it was false and accordingly, the Revised Proposed Order seeks to enjoin the literally false claim “Unparalleled precision.” Natera’s concerns that the injunction would reach other claims in its advertisements not included on

the Jury Verdict Form is therefore without merit. *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 206 (3d Cir. 2014) (“the injunction is not overbroad because it is limited to reaching claims that are literally false”)

C. Natera’s Pediatric Claim Is Literally False

The Jury found it was literally false for Natera to claim that Prospera is “Highly sensitive across a range of rejection types and patients” including patients below 18 years of age. D.I. 329 at 13. Indeed, Natera’s former Chief Medical Officer Dr. Paul Billings testified that he did not believe he could make “any claims about pediatric patients based on the Sigdel data set.” 3/8, 217:14-19. And Natera’s General Manager of the Organ Transplant Group Solomon Moshkevich testified: “We did not investigate sufficiently to make specific claims about – about test performance in the pediatric population because there were no cases of rejection in our study from the pediatric population.” *Id.* at 135:4-15.

The Tweet at issue claims “Prospera Kidney is now validated for use for kidney transplant recipients ages 10+.” D.I. 353-11. The Tweet cites no study to support its claim (*id.*), and there is no reason for clinicians to believe it relies on anything other than the Sigdel Study, which the Jury found—and Natera’s executives agreed—does not support claims that Prospera is validated in pediatric patients. While the Rabin Declaration claims that the statement is “based on a subsequent validation study of samples from a subset of patients ages 10 to 17”, it

too fails to cite which study, or specify that the samples are not the same as the biased samples used in Sigdel. D.I. 358 ¶ 8.

Without a new study to support Prospera's efficacy in pediatric patients, the Tweet is not colorably different from the claim the Jury found to be literally false and should be enjoined. *See TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 882 (Fed. Cir. 2011) ("The primary question on contempt should be whether the newly accused product is so different from the product previously found to infringe that it raises 'a fair ground of doubt to the wrongfulness of the defendant's conduct.'" (citing *Cal. Artificial Stone Paving Co. v. Molitor*, 113 U.S. 609, 618 (1985))). Because there is no reason to believe the Tweet is based on data other than the data from the Sigdel Study, there is no fair ground of doubt that Natera's claims of efficacy in pediatric patients are false. The proposed injunction would require Natera to identify the scientific support for any such claim. *See Revised Proposed Order at E.*

IV. CONCLUSION

CareDx respectfully requests that the Court grant its request for a permanent injunction based on its Revised Proposed Order.

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Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order for All Cases. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 2,464 words, excluding the case caption, signature block, table of contents and table of authorities.

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